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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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20583	7590	02/03/2009	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			GANESAN, SUBA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/603,115	Applicant(s) DING ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 111-170 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 111-170 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/21/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 111-170 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that the amended language including "wherein at least a portion of the undercoat covers at least a portion of the metallic stent portion, wherein... the topcoat... at least partially covers the portion of the undercoat that covers at least a portion of the metallic stent portion" defines a configuration in which the stent is the bottom layer, the undercoat is on top of the stent, and the topcoat is on top of the undercoat.

2. Examiner disagrees. The claim merely requires that the layers exist in a relationship with one another such that they are "covered." For example, a sandwich is covered from the top and bottom with bread, but the top slice also covers the bottom slice, regardless of what toppings exist in the middle of the sandwich.

3. In the instant case, the topcoat of Lee (graft A) covers the portion of the undercoat 10 that covers stent 30 from the bottom. Graft A, by virtue of its location above both stent 30 and undercoat 10, covers the portion of the undercoat that covers the stent.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 111,124, 125, 139-141,154-155, 169-170 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (U.S. Pat. No.: 5,123,917).

6. Lee discloses a metallic stent 30 wherein at least part of the metallic stent is covered with a coating (graft A, fig. 1) for release of a biologically active material, the coating comprising an undercoat 10 comprising hydrophobic elastomeric material (polyurethane) incorporating an amount of biologically active material (for example heparin, col. 4 lines 58-61). The topcoat of Lee (graft A) covers the portion of the undercoat 10 that covers stent 30 from the bottom. The topcoat (graft A), by virtue of its location above both stent 30 and undercoat 10, covers the portion of the undercoat 10 that covers the stent 30.

7. The coating further comprises a topcoat 20 comprising a biostable non-thrombogenic polymeric material which is different from the hydrophobic elastomeric material (PTFE, Dacron, col. 5 lines 3-7) wherein the topcoat is free of an elutable material (col. 5 lines 7-10, noting that drug impregnation is an option, not a necessity). The topcoat is a barrier which the Examiner is considering to be a control of the release profile of the biologically active material (col. 3 lines 54-67).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 112, 113, 129, 130, 142, 143, 159, 160 are rejected under 35 U.S.C.

103(a) as being unpatentable over Lee (U.S. Pat. No.: 5,123,917) in view of Berg et al. (U.S. Pat. No.: 5,464,650).

10. Lee is explained supra. However, Lee does not disclose the undercoat comprising an ethylene vinyl acetate copolymer material. Berg teaches the use of ethylene vinyl acetate copolymers as a suitable substrate for drug eluting stents (col. 4 lines 19-39, col. 5 line 1). Therefore it would have been obvious to one of ordinary skill in the art to modify the undercoat of Lee to comprise an ethylene vinyl acetate copolymer as taught by Berg, since it is within the skill of an ordinary worker in the art to select a particular material from a given set of known materials suitable for an intended purpose or use. In the instant case, Berg teaches the suitability of ethylene vinyl acetate copolymers as implant material and as drug-eluting material.

11. Claims 114-116, 118-121, 128, 131-138, 144-146, 148-151, 158, 161-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Pat. No.: 5,123,917) in view of Berg et al. (U.S. Pat. No.: 5,464,650) as applied above, further in view of Mitchell et al. (5,288,711).

12. Lee in view of Berg teaches a coated vascular stent as above however Lee and Berg appear to lack the coating comprising an antibiotic. Mitchell et al. teaches a stent comprising an antibiotic (Rapamycin) to inhibit proliferation of vascular smooth muscle cells (col. 3, lines 7-31). It would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic, as taught by Mitchell et al., to a

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coated vascular stent as per Lee and Berg, in order to inhibit proliferation of vascular smooth muscle cells.

13. Claims 117, 122,123, 126, 127, 147, 152, 153, 156, 157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (U.S. Pat. No.: 5,123,917) in view of Mitchell et al. (5,288,711).

14. Lee teaches a coated vascular stent as above however Lee lacks the coating comprising an antibiotic. Mitchell et al. teaches a stent comprising an antibiotic (Rapamycin) to inhibit proliferation of vascular smooth muscle cells (col. 3, lines 7-31). It would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic, as taught by Mitchell et al., to a coated vascular stent as per Lee, in order to inhibit proliferation of vascular smooth muscle cells.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774